AMERICAN ACADEMY OF AUDIOLOGY

8300 Greensboro Drive, Suite 750, McLean, VA 22102-3611

September 30, 2000

The Honorable Donna E. Shalala
Secretary, Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Madam Secretary:

We are writing on behalf of the nearly 7,000 members of the American Academy of Audiology (AAA) and 1200 members of the Academy of Dispensing Audiologists (ADA) with regard to the Food and Drug Administration's (FDA) rulemaking concerning the conditions for the sale of hearing instruments. Both Academies are dedicated to assuring the provision of quality hearing care through professional development, education, research, and increased public awareness of hearing disorders.

We understand that FDA recently finalized its proposed hearing aid regulation and has forwarded it to the Department of Health and Human Services (HHS) for review. As you know, FDA's Advanced Notice of Proposed Rulemaking regarding hearing aids was first released seven years ago. Since that time, the content of the agency's pending proposal has been a topic of considerable debate and speculation. Numerous groups have expressed widely diverging views as to how hearing aids should be regulated.

Given this climate of controversy, we felt it important to share with you what we believe should be the overriding concern addressed in FDA's proposed hearing aid regulation: Ensuring that individuals who are hearing-disabled receive the absolute highest quality of care. Indeed, approximately 28 million Americans suffer from hearing difficulties, and this number is growing as the population ages, noise exposure increases and other causative circumstances are included in the equation. It is critical that FDA's regulatory scheme, above all, serves to protect the interests of this rapidly expanding population of hearing-disabled individuals.

To that end, we believe it is essential that every person seeking treatment of hearing disorders through the use of hearing instruments receive a comprehensive audiologic evaluation prior to purchase. This evaluation should include any and all necessary procedures to determine: (i) a thorough history of hearing loss; (ii) auditory sensitivity (thresholds); (iii) speech recognition capabilities; (iv) type of hearing loss; (v) need for referral to a physician; and (vi) candidacy for amplification devices. The purpose of such an evaluation is not to select or fit a hearing aid, but, rather to assess the functional status of the auditory system, and to assure that hearing instruments are, in fact, an appropriate strategy for the patient.

We firmly believe that it is in the best interests of hearing-disabled individuals, the comprehensive audiologic evaluation described above be completed by an audiologist who is licensed or registered in the state wherein the evaluation is administered. By virtue of their graduate education, professional training and well-documented practice patterns, audiologists are the individuals best qualified to both perform and interpret the pre-purchase audiologic evaluation. Furthermore, the scope of practice of audiology is well defined in nearly each of the 50 states wherein licensure or registration has been mandated. In these states, licensure or registration is the official legal mechanism for ensuring that practicing audiologists satisfy applicable educational and training standards, and adhere to standards of ethical conduct.

Indeed, Congress is consistently recognizing state licensure and registration as the appropriate vehicle for identifying qualified audiologists. For example, in 1994, Congress enacted a statutory definition of the term □udiologist for the Medicare program that relied primarily on state licensure and registration as the mechanism for identifying audiologists who are qualified to participate in that program. Just recently, in the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Bill, 2001, HHS was again urged by Congress to promulgate regulations that rely upon state licensure as the mechanism for identifying qualified audiologists. (Report 106-645, p.108).

Thus, as HHS reviews FDA's hearing aid proposal, we urge the Department to ensure that the proposed regulation incorporates a mandatory, comprehensive, pre-purchase audiologic evaluation performed and interpreted by a qualified, state-licensed or registered audiologist. In our view, this, more than anything else, will help to protect the interests of hearing-disabled individuals and to optimize the quality of care they receive.

We appreciate your attention to this important issue. The hearing healthcare community and the millions of Americans who suffer from hearing difficulties look forward to the promulgation of FDA's proposed regulation. If we can provide you with any additional information regarding this matter, please do not hesitate to contact us.

Sincerely,

Robert G. Glaser, Ph.D.,
President
American Academy of Audiology

James McDonald, Sc.D.,
President
Academy of Dispensing Audiologists

cc: Dr. Jane Henney
Dr. Margaret Ann Hamburg